c.) Remarks

Office Action of May 16, 2005

Claims 1-4, 6, 8-9, 11-15, and 17-22 are pending. The following claim rejection has been entered:

1) Rejection of claims 1-4, 6, 8-9, 11-15, and 17-22 under 35 USC § 103(a) as being unpatentable over U.S. Patent 4,851,221 to Pak et al ("Pak") in view of "Calcium and Serum Cholesterol", Nutrition Review, vol. 25, no. 10, pp. 298-300, 1967 (hereinafter "Nutrition Review") or Mitchell et al, "The Effect of Oral Calcium on Cholesterol Metabolism", Journal of Atherosclerosis Research, vol. 8, pp. 913-922, 1968. ("hereinafter "Mitchell").

1. Rejection of Claims 1-4, 6, 8-9, 11-15, and 17-22 under 35 USC § 103(a)

The examiner has rejected claims 1-4, 6, 8-9, 11-15, and 17-22 under 35 USC § 103(a) as being unpatentable over Pak in view of Nutrition Review or Mitchell. The examiner asserts that Pak discloses the administration of a calcium supplemental composition comprising calcium citrate at a dose of 1 g/day (60 meq/day) or 1.5-2.75 g/day to a postmenopausal woman for treating various conditions such as hypoparathyroidism, osteoporosis, bone loss, hyperphosphatemia, and hypertension. The examiner states that Pak discloses a daily administration and that the composition of Pak is prepared from pre-mix preparation with a calcium/citrate molar ratio of 1.25 of citric acid and a calcium compound such as calcium hydroxide. However, the examiner recognizes that the Pak reference 1) does not expressly disclose the employment of a calcium composition in methods of increasing an HDL level in plasma or a ratio of HDL to LDL in a postmenopausal woman, 2) does not expressly disclose measuring the HDL level in said woman, and importantly, **3) does not expressly disclose the**

administration of the calcium composition for at least about two months. (see pending office action at page 3). The examiner asserts that Nutrition Review teaches that oral calcium supplements are known to have hypocholesteremic effect in a person or subject with raised serum cholesterol and that cholesterol levels are known to be measured before and at the end of calcium administration. The examiner also asserts that Mitchell teaches that serum cholesterol levels are known to be measured using an Auto Analyzer (a known method) to test the effect of oral calcium on cholesterol metabolism. The examiner concludes that "it would have been obvious to a person of ordinary skill in the art at the time the invention was made to administer the calcium composition to a postmenpausal woman daily or at least two or six months for increasing a high-density lipoprotein (HDL) in plasma or a ratio of HDL to LDL in said postmenopausal woman; and to measure the high-density lipoprotein level in [a] postmenopausal woman [who has been administered] calcium citrate for increasing HDL level." Applicants respectfully traverse the rejection.

In the present office action, the examiner dismisses the arguments offered by the applicants in their last submission that the combination under § 103(a) is improper because either or both of Mitchell and Nutrition Review teach away from Pak. With respect to Nutrition Review, the abstract of that reference teaches "[t]here is no evidence that this effect is maintained for longer than three or four weeks, and there seems to be no justification for using oral calcium as a means of reducing serum cholesterol levels." (emphasis added). In this way, Nutrition Review clearly teaches away from administration of oral calcium for longer than three or four weeks. With respect to Mitchell, the abstract of that reference teaches: "[t]he serum cholesterol and triglyceride levels showed little change from the basal levels during the calcium supplementation period." Thus, Mitchell also teaches away from the claimed invention.

The examiner relies on MPEP 2123 (and Federal Circuit cases cited therein), asserting that despite any "teaching away", a reference can still anticipate a claim. Applicants assert that MPEP 2123 and the cases cited therein are not applicable to the pending rejection. The MPEP provision cited by the examiner merely stands for the rather unremarkable propositions that a patent reference is prior art for all it contains and that any of the disclosed embodiments in a patent reference (not solely the preferred embodiment) can render a claim unpatentable. MPEP 2123 clearly addresses only the case of rejections over a single reference (i.e., rejections based upon anticipation under § 102). The cases cited therein only state that the issue of "teaching away" is not relevant to an anticipation analysis (i.e., a patentability analysis under § 102). They stand for the proposition that if a single reference discloses an invention, it is anticipated under § 102, regardless of whether or not the reference also disparages the invention or treats it as a less-than-preferred embodiment. In other words, one part of a reference cannot be said to "teach away" from another part **of the same reference**. (*See Celeritas Technol., Ltd. v. Rockwell Int'l.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998); this case is referenced in MPEP 2123). This is not the case for the pending rejection. The pending rejection is one under § 103(a) for obviousness. In this case, a "teaching away" analysis is very relevant to a rejection over a combination of references **where the teaching of one reference teaches away from the teaching of the other reference.**

The examiner's argument based on MPEP 2123 is further inapposite because that provision merely states that less than optimal embodiments are proper for anticipation and can be used to properly deny patentability so long as they are disclosed. This is inapposite to the pending rejection even if it is possible to extend MPEP 2123 to the context of obviousness under § 103(a) (although such an extension is not proper under the plain language of that provision)

because the secondary references of Nutrition Review and Mitchell do not teach that a 2-month (or longer) therapy is "less than optimal"; rather they teach that such therapy **is not useful**. Thus, even if MPEP 2123 is assumed to be applicable to a § 103(a) analysis (which it is not), the facts of the present case are very different than the scenario addressed in MPEP 2123 and provide a much more compelling basis for patentability.

Applicants assert that the examiner's arguments dismissing the applicant's position as stated in their last response is incorrect as to both the law and the facts of this case. Accordingly, applicants respectfully request that the examiner withdraw the pending rejection of all pending claims under § 103(a).

d.) Conclusions

In light of the Applicants' argument, Applicants respectfully request withdrawal of the outstanding rejections and allowance of the pending claims. If any issues remain outstanding, please contact the undersigned for resolution of the same.

Applicants do not believe that any fees are due or associated with this filing. However, if applicants are in error and any fees are owing, the Commissioner may charge Deposit Account No. 06-2375, under Order No. P02194US0/10104570, from which the undersigned is authorized to draw.

Respectfully submitted,

Date: June 8, 2005

By: _____

Gino Catena
Reg. No 45,546
FULBRIGHT & JAWORSKI L.L.P.
1301 McKinney, Suite 5100
Houston, Texas 77010-3095
Tel: (713) 651-5144
Fax: (713) 651-5246